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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/894,767 02/23/98 WEITSCHIES W SCH1526

023599 HM22/0828
MILLEN, WHITE, ZELAND & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON VA 22201

EXAMINER

DO, P

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

08/28/01

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

08/894,767

Applicant(s)

WEITSCHIES ET AL.

Examiner

Pensee T. Do

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 8-15, 25 and 39.Claim(s) objected to: 22.Claim(s) rejected: 1, 2, 4, 5, 16-18 and 22-24.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See attach d detailed action

Art Unit: 1641

DETAILED ACTION

1. The amendment filed on July 13, 2001 has been acknowledged and entered as paper no. 17.

Claim Objections

2. Claim 22 is objected to because of the following informalities: claim 22 depends on a non-elected claim 3. Appropriate correction is required.

Withdrawn Rejection(s)

3. Rejections under 35 U.S.C. 112, first paragraph and the judicially created doctrine of obviousness type double patenting in the previous office action are withdrawn herein.

Maintained Rejections

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 3220442 A (TDK Corp).

TDK Corp. teaches a method of determining the concentration of antigen/antibody in a liquid sample, comprising suspending magnetic fine particles fixed with antibody/antigen binding specifically with the analyte, the antigen/antibody, in a liquid sample containing said analyte to

Art Unit: 1641

cause agglutination of the magnetic fine particles by antigen-antibody reaction; applying a magnetic field to the suspension liquid containing the agglutinated matter to align the magnetic fine particles; stopping the magnetic field; and measuring the remanent magnetic flux density of the agglutinated matter to determine the particle size of the agglutinated matter. (See abstract).

6. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (EP0180384 July 1986).

Cohen et al. teach a stable magnetically responsive reagent carrier, substantially remanent-free particulate reagent carrier useful in immunoassay procedures. The particulate reagent carrier comprises particles or beads, each formed of a water-insoluble matrix, e.g. a gel, swellable in an aqueous solution having colloiddally dispersed therein superparamagnetic granules. The size range of the particles is from 5 to 500 nanometers. The reagent carrier comprises a polymeric matrix, in which the magnetic substance is incorporated, is water insoluble but swellable in aqueous medium. (See pages 4-6).

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3220442 (TDK, Corp.) further in view of Cohen et al.

Art Unit: 1641

TDK, Corp. has been discussed above.

However, TDK, Corp. does not teach the particle size range from 1-1000 nm or the ferromagnetic and ferrimagnetic substances are stabilized with a shell that is made of oligomeric or polymeric carbohydrates, proteins, peptides, nucleotides, surfactants, synthetic polymers and/or lipids.

Cohen et al. teach the particle size range from 5-500 nm and a polymeric matrix.

It would have been obvious to one of ordinary skill in the art to use particles of size range taught by Cohen et al. in the method of TDK, Corp. because such size range falls within the size range of colloidal particles.

Response to Arguments

9. Applicant's arguments filed February 21, 2001 have been fully considered but they are not persuasive.

10. Applicant argues that both TDK and Cohen fail to teach a heterogenous assay. Applicant also argues that "heterogenous immunoassay is recited in the body of the claim.

Heterogenous immunoassay is defined or well known as a method of assay in which separation of the bound from the unbound is required. In the method of TDK Corp., after the analytes are labeled with magnetic particles bound with analyte-specific antibody or antigen, a magnetic field is generated to separate the analytes which bind to the magnetic particles from the unbound analytes. (See abstract Use/advantage). Thus, the method of TDK Corp. is a heterogenous immunoassay.

Art Unit: 1641

Cohen teaches that the particles can be complexed with ligands of the specific chemicals to be recovered from suspensions containing other particulate solids. Once complexed, these specific chemicals can be magnetically separated and retrieved. The magnetic particles can be used in a heterogenous immunoassay which requires magnetic separation. (See page 14, 1st paragraph).

Allowable Subject Matter

11. Claims 8-15, 25 and 39 are allowed over the prior arts.

The prior arts do not teach the intrinsic Neelian relaxation times of the ferromagnetic and ferrimagnetic substances that are greater than the measuring time.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri from 7 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 08/894,767

Page 6

Art Unit: 1641

Pensee T. Do
Patent Examiner
August 25, 2001



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

08/26/01